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H. R. 5533

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Read twice and referred to the Committee on Health, Education, Labor, and
Pensions

AN ACT

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Biodefense and Pan-
3 demic Vaccine and Drug Development Act of 2006”.

4 **SEC. 2. TABLE OF CONTENTS.**

5 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Biomedical Advanced Research and Development Authority; National
Biodefense Science Board.

Sec. 4. Clarification of countermeasures covered by Project BioShield.

Sec. 5. Technical assistance.

Sec. 6. Procurement.

6 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-**
7 **MENT AUTHORITY; NATIONAL BIODEFENSE**
8 **SCIENCE BOARD.**

9 Title III of the Public Health Service Act (42 U.S.C.
10 241 et seq.) is amended by inserting after section 319K
11 the following:

12 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**
13 **VELOPMENT AUTHORITY.**

14 “(a) BIOMEDICAL ADVANCED RESEARCH AND DE-
15 VELOPMENT AUTHORITY.—

16 “(1) ESTABLISHMENT.—There is established
17 within the Department of Health and Human Serv-
18 ices the Biomedical Advanced Research and Develop-
19 ment Authority.

20 “(2) IN GENERAL.—The Secretary shall coordi-
21 nate and oversee the acceleration of countermeasure

1 and product advanced research and development
2 by—

3 “(A) facilitating collaboration among the
4 Department of Health and Human Services,
5 other Federal agencies, relevant industries, aca-
6 demia, and other persons, with respect to such
7 advanced research and development;

8 “(B) promoting countermeasure and prod-
9 uct advanced research and development;

10 “(C) facilitating contacts between inter-
11 ested persons and the offices or employees au-
12 thorized by the Secretary to advise such persons
13 regarding requirements under the Federal
14 Food, Drug, and Cosmetic Act and under sec-
15 tion 351 of this Act; and

16 “(D) promoting innovation to reduce the
17 time and cost of countermeasure and product
18 advanced research and development.

19 “(3) DIRECTOR.—The BARDA shall be headed
20 by a Director (referred to in this section as the ‘Di-
21 rector’) who shall be appointed by the Secretary and
22 to whom the Secretary shall delegate such functions
23 and authorities as necessary to implement this sec-
24 tion.

25 “(4) DUTIES.—

1 “(A) COLLABORATION.—To carry out the
2 purpose described in paragraph (2)(A), the Sec-
3 retary shall—

4 “(i) facilitate and increase the expedi-
5 tious and direct communication between
6 the Department of Health and Human
7 Services and relevant persons with respect
8 to countermeasure and product advanced
9 research and development, including by—

10 “(I) facilitating such communica-
11 tion regarding the processes for pro-
12 curing such advanced research and
13 development with respect to qualified
14 countermeasures and qualified pan-
15 demic or epidemic products of inter-
16 est; and

17 “(II) soliciting information about
18 and data from research on potential
19 qualified countermeasures and quali-
20 fied pandemic or epidemic products
21 and related technologies;

22 “(ii) at least annually—

23 “(I) convene meetings with rep-
24 resentatives from relevant industries,
25 academia, other Federal agencies,

1 international agencies as appropriate,
2 and other interested persons;

3 “(II) sponsor opportunities to
4 demonstrate the operation and effec-
5 tiveness of relevant biodefense coun-
6 termeasure technologies; and

7 “(III) convene such working
8 groups on countermeasure and prod-
9 uct advanced research and develop-
10 ment as the Secretary may determine
11 are necessary to carry out this sec-
12 tion; and

13 “(iii) carry out the activities described
14 in section 6 of the Biodefense and Pan-
15 demic Vaccine and Drug Development Act
16 of 2006.

17 “(B) SUPPORT ADVANCED RESEARCH AND
18 DEVELOPMENT.—To carry out the purpose de-
19 scribed in paragraph (2)(B), the Secretary
20 shall—

21 “(i) conduct ongoing searches for, and
22 support calls for, potential qualified coun-
23 termeasures and qualified pandemic or epi-
24 demic products;

1 “(ii) direct and coordinate the coun-
2 termeasure and product advanced research
3 and development activities of the Depart-
4 ment of Health and Human Services;

5 “(iii) establish strategic initiatives to
6 accelerate countermeasure and product ad-
7 vanced research and development and in-
8 novation in such areas as the Secretary
9 may identify as priority unmet need areas;
10 and

11 “(iv) award contracts, grants, cooper-
12 ative agreements, and enter into other
13 transactions, for countermeasure and prod-
14 uct advanced research and development.

15 “(C) FACILITATING ADVICE.—To carry out
16 the purpose described in paragraph (2)(C) the
17 Secretary shall—

18 “(i) connect interested persons with
19 the offices or employees authorized by the
20 Secretary to advise such persons regarding
21 the regulatory requirements under the
22 Federal Food, Drug, and Cosmetic Act
23 and under section 351 of this Act related
24 to the approval, clearance, or licensure of

1 qualified countermeasures or qualified pan-
2 demic or epidemic products; and

3 “(ii) ensure that, with respect to per-
4 sons performing countermeasure and prod-
5 uct advanced research and development
6 funded under this section, such offices or
7 employees provide such advice in a manner
8 that is ongoing and that is otherwise des-
9 ignated to facilitate expeditious develop-
10 ment of qualified countermeasures and
11 qualified pandemic or epidemic products
12 that may achieve such approval, clearance,
13 or licensure.

14 “(D) SUPPORTING INNOVATION.—To carry
15 out the purpose described in paragraph (2)(D),
16 the Secretary may award contracts, grants, and
17 cooperative agreements, or enter into other
18 transactions, such as prize payments, to pro-
19 mote—

20 “(i) innovation in technologies that
21 may assist countermeasure and product
22 advanced research and development;

23 “(ii) research on and development of
24 research tools and other devices and tech-
25 nologies; and

1 “(iii) research to promote strategic
2 initiatives, such as rapid diagnostics, broad
3 spectrum antimicrobials, and vaccine man-
4 ufacturing technologies.

5 “(5) TRANSACTION AUTHORITIES.—

6 “(A) OTHER TRANSACTIONS.—In carrying
7 out the functions under subparagraph (B) or
8 (D) of paragraph (4), the Secretary shall have
9 authority to enter into other transactions for
10 countermeasure and product advanced research
11 and development.

12 “(B) EXPEDITED AUTHORITIES.—

13 “(i) IN GENERAL.—In awarding con-
14 tracts, grants, and cooperative agreements,
15 and in entering into other transactions
16 under subparagraph (B) or (D) of para-
17 graph (4), the Secretary shall have the ex-
18 pedited procurement authorities, the au-
19 thority to expedite peer review, and the au-
20 thority for personal services contracts, sup-
21 plied by subsections (b), (c), and (d) of
22 section 319F–1.

23 “(ii) APPLICATION OF PROVISIONS.—
24 Provisions in such section 319F–1 that
25 apply to such authorities and that require

1 institution of internal controls, limit re-
2 view, provide for Federal Tort Claims Act
3 coverage of personal services contractors,
4 and commit decisions to the discretion of
5 the Secretary shall apply to the authorities
6 as exercised pursuant to this paragraph.

7 “(iii) AUTHORITY TO LIMIT COMPETI-
8 TION.—For purposes of applying section
9 319F–1(b)(1)(D) to this paragraph, the
10 phrase ‘BioShield Program under the
11 Project BioShield Act of 2004’ shall be
12 deemed to mean the countermeasure and
13 product advanced research and develop-
14 ment program under this section.

15 “(iv) AVAILABILITY OF DATA.—The
16 Secretary may require that, as a condition
17 of being awarded a contract, grant, cooper-
18 ative agreement, or other transaction
19 under subparagraph (B) or (D) of para-
20 graph (4), a person make available to the
21 Secretary on an ongoing basis, and submit
22 upon request to the Secretary, relevant
23 data related to or resulting from counter-
24 measure and product advanced research

1 and development carried out pursuant to
2 this section.

3 “(C) ADVANCE PAYMENTS; ADVER-
4 TISING.—The authority of the Secretary to
5 enter into contracts under this section shall not
6 be limited by section 3324(a) of title 31, United
7 States Code, or by section 3709 of the Revised
8 Statutes of the United States (41 U.S.C. 5).

9 “(D) MILESTONE-BASED PAYMENTS AL-
10 LOWED.—In awarding contracts, grants, and
11 cooperative agreements, and in entering into
12 other transactions, under this section, the Sec-
13 retary may use milestone-based awards and
14 payments.

15 “(E) FOREIGN NATIONALS ELIGIBLE.—
16 The Secretary may under this section award
17 contracts, grants, and cooperative agreements
18 to, and may enter into other transactions with,
19 highly qualified foreign national persons outside
20 the United States, alone or in collaboration with
21 American participants, when such transactions
22 may inure to the benefit of the American people
23 and are consistent with National security.

24 “(F) ESTABLISHMENT OF ADVANCED RE-
25 SEARCH CENTERS.—The Secretary may estab-

lish one or more federally-funded research and development centers, or university-affiliated research centers in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)), provided that such centers are consistent and complementary with the duties described in paragraph (4), and are consistent and complementary with, and deemed necessary after considering the availability of, existing federally-supported basic research programs.

“(6) VULNERABLE POPULATIONS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to the emergency health security needs of children and other vulnerable populations.

“(7) PERSONNEL AUTHORITIES.—

“(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—In addition to any other personnel authorities, the Secretary may—

1 “(i) without regard to those provisions
2 of title 5, United States Code, governing
3 appointments in the competitive service,
4 appoint highly qualified individuals to sci-
5 entific or professional positions in
6 BARDA, such as program managers, to
7 carry out this section; and

8 “(ii) compensate them in the same
9 manner in which individuals appointed
10 under section 9903 of such title are com-
11 pensated, without regard to the provisions
12 of chapter 51 and subchapter III of chap-
13 ter 53 of such title relating to classification
14 and General Schedule pay rates.

15 “(B) SPECIAL CONSULTANTS.—In carrying
16 out this section, the Secretary may—

17 “(i) appoint special consultants pursu-
18 ant to section 207(f); and

19 “(ii) accept voluntary and uncompen-
20 sated services.

21 “(c) INAPPLICABILITY OF CERTAIN PROVISIONS.—

22 “(1) DISCLOSURE.—

23 “(A) IN GENERAL.—The Secretary shall
24 withhold from disclosure under section 552 of
25 title 5, United States Code, specific technical

1 data or scientific information that is created or
2 obtained during the countermeasure and prod-
3 uct advanced research and development funded
4 by the Secretary that reveal vulnerabilities of
5 existing medical or public health defenses
6 against biological, chemical, nuclear, or radio-
7 logical threats. Such information shall be
8 deemed to be information described in section
9 552(b)(3) of title 5, United States Code.

10 “(B) OVERSIGHT.—Information subject to
11 nondisclosure under subparagraph (A) shall be
12 reviewed by the Secretary every 5 years to de-
13 termine the relevance or necessity of continued
14 nondisclosure.

15 “(2) FEDERAL ADVISORY COMMITTEE ACT.—
16 Section 14 of the Federal Advisory Committee Act
17 (5 U.S.C. App.) shall not apply to a working group
18 of BARDA or to the National Biodefense Science
19 Board under section 319M.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
21 purpose of carrying out advanced research and develop-
22 ment under this section, there are authorized to be appro-
23 priated \$160,000,000 for each of the fiscal years 2007
24 and 2008. Such authorizations are in addition to other
25 authorizations of appropriations that are available for

1 such purpose. Amounts appropriated under the preceding
2 sentence are available until expended.

3 “(e) DEFINITIONS.—For purposes of this section:

4 “(1) BARDA.—The term ‘BARDA’ means the
5 Biomedical Advanced Research and Development
6 Authority.

7 “(2) OTHER TRANSACTIONS.—The term ‘other
8 transactions’ means transactions, other than pro-
9 curement contracts, grants, and cooperative agree-
10 ments, such as the Secretary of Defense may enter
11 into under section 2371 of title 10, United States
12 Code.

13 “(3) QUALIFIED COUNTERMEASURE.—The term
14 ‘qualified countermeasure’ has the meaning given
15 such term in section 319F–1.

16 “(4) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
17 UCT.—The term ‘qualified pandemic or epidemic
18 product’ has the meaning given the term in section
19 319F–3.

20 “(5) ADVANCED RESEARCH AND DEVELOP-
21 MENT.—

22 “(A) IN GENERAL.—The term ‘advanced
23 research and development’ means, with respect
24 to a product that is or may become a qualified

1 countermeasure or a qualified pandemic or epi-
2 demic product, activities that predominantly—

3 “(i) are conducted after basic research
4 and preclinical development of the product;
5 and

6 “(ii) are related to manufacturing the
7 product on a commercial scale and in a
8 form that satisfies the regulatory require-
9 ments under the Federal Food, Drug, and
10 Cosmetic Act or under section 351 of this
11 Act.

12 “(B) ACTIVITIES INCLUDED.—The term
13 under subparagraph (A) includes—

14 “(i) testing of the product to deter-
15 mine whether the product may be ap-
16 proved, cleared, or licensed under the Fed-
17 eral Food, Drug, and Cosmetic Act or
18 under section 351 of this Act for a use
19 that is or may be the basis for such prod-
20 uct becoming a qualified countermeasure
21 or qualified pandemic or epidemic product,
22 or to help obtain such approval, clearance,
23 or license;

1 “(ii) design and development of tests
2 or models, including animal models, for
3 such testing;

4 “(iii) activities to facilitate manufac-
5 ture of the product on a commercial scale
6 with consistently high quality, as well as to
7 improve and make available new tech-
8 nologies to increase manufacturing surge
9 capacity;

10 “(iv) activities to improve the shelf-life
11 of the product or technologies for admin-
12 istering the product; and

13 “(v) such other activities as are part
14 of the advanced stages of testing, refine-
15 ment, improvement, or preparation of the
16 product for such use and as are specified
17 by the Secretary.

18 “(6) RESEARCH TOOL.—The term ‘research
19 tool’ means a device, technology, biological material,
20 reagent, animal model, computer system, computer
21 software, or analytical technique that is developed to
22 assist in the discovery, development, or manufacture
23 of qualified countermeasures or qualified pandemic
24 or epidemic products.

1 “(7) PROGRAM MANAGER.—The term ‘program
2 manager’ means an individual appointed to carry out
3 functions under this section and authorized to pro-
4 vide project oversight and management of strategic
5 initiatives.

6 “(8) PERSON.—The term ‘person’ includes an
7 individual, partnership, corporation, association, en-
8 tity, or public or private corporation, and a Federal,
9 State, or local government agency or department.

10 **“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND**
11 **WORKING GROUPS.**

12 “(a) IN GENERAL.—

13 “(1) ESTABLISHMENT AND FUNCTION.—The
14 Secretary shall establish the National Biodefense
15 Science Board (referred to in this section as the
16 ‘Board’) to provide expert advice and guidance to
17 the Secretary on scientific, technical and other mat-
18 ters of special interest to the Department of Health
19 and Human Services regarding current and future
20 chemical, biological, nuclear, and radiological agents,
21 whether naturally occurring, accidental, or delib-
22 erate.

23 “(2) MEMBERSHIP.—The membership of the
24 Board shall be comprised of individuals who rep-

1 resent the Nation’s preeminent scientific, public
2 health, and medical experts, as follows—

3 “(A) such Federal officials as the Sec-
4 retary may determine are necessary to support
5 the functions of the Board;

6 “(B) four individuals representing the
7 pharmaceutical, biotechnology, and device in-
8 dustries;

9 “(C) four individuals representing aca-
10 demia; and

11 “(D) five other members as determined ap-
12 propriate by the Secretary.

13 “(3) TERM OF APPOINTMENT.—A member of
14 the Board described in subparagraph (B), (C), or
15 (D) of paragraph (2) shall serve for a term of 3
16 years, except that the Secretary may adjust the
17 terms of the initial Board appointees in order to
18 provide for a staggered term of appointment for all
19 members.

20 “(4) CONSECUTIVE APPOINTMENTS; MAXIMUM
21 TERMS.—A member may be appointed to serve not
22 more than 3 terms on the Board and may serve not
23 more than 2 consecutive terms.

24 “(5) DUTIES.—The Board shall—

1 “(A) advise the Secretary on current and
2 future trends, challenges, and opportunities pre-
3 sented by advances in biological and life
4 sciences, biotechnology, and genetic engineering
5 with respect to threats to biodefense or public
6 health security posed by naturally occurring in-
7 fectious diseases and chemical, biological, radio-
8 logical, and nuclear agents;

9 “(B) at the request of the Secretary, re-
10 view and consider any information and findings
11 received from the working groups established
12 under subsection (b); and

13 “(C) at the request of the Secretary, pro-
14 vide recommendations and findings for ex-
15 panded, intensified, and coordinated biodefense
16 research and development activities.

17 “(6) MEETINGS.—

18 “(A) INITIAL MEETING.—Not later than
19 one year after the date of enactment of the Bio-
20 defense and Pandemic Vaccine and Drug Devel-
21 opment Act of 2006, the Secretary shall hold
22 the first meeting of the Board.

23 “(B) SUBSEQUENT MEETINGS.—The
24 Board shall meet at the call of the Secretary,
25 but in no case less than twice annually.

1 “(7) VACANCIES.—Any vacancy in the Board
2 shall not affect its powers, but shall be filled in the
3 same manner as the original appointment.

4 “(8) CHAIRPERSON.—The Secretary shall ap-
5 point a chairperson from among the members of the
6 Board.

7 “(9) POWERS.—

8 “(A) HEARINGS.—The Board may hold
9 such hearings, sit and act at such times and
10 places, take such testimony, and receive such
11 evidence as the Board considers advisable to
12 carry out this subsection.

13 “(B) POSTAL SERVICES.—The Board may
14 use the United States mails in the same man-
15 ner and under the same conditions as other de-
16 partments and agencies of the Federal Govern-
17 ment.

18 “(10) PERSONNEL.—

19 “(A) EMPLOYEES OF THE FEDERAL GOV-
20 ERNMENT.—A member of the Board that is an
21 employee of the Federal Government may not
22 receive additional pay, allowances, or benefits
23 by reason of the member’s service on the
24 Board.

1 “(B) OTHER MEMBERS.—A member of the
2 Board that is not an employee of the Federal
3 Government may be compensated at a rate not
4 to exceed the daily equivalent of the annual rate
5 of basic pay prescribed for level IV of the Exec-
6 utive Schedule under section 5315 of title 5,
7 United States Code, for each day (including
8 travel time) during which the member is en-
9 gaged in the actual performance of duties as a
10 member of the Board.

11 “(C) TRAVEL EXPENSES.—Each member
12 of the Board shall receive travel expenses, in-
13 cluding per diem in lieu of subsistence, in ac-
14 cordance with applicable provisions under sub-
15 chapter I of chapter 57 of title 5, United States
16 Code.

17 “(D) DETAIL OF GOVERNMENT EMPLOY-
18 EES.—Any Federal Government employee may
19 be detailed to the Board with the approval for
20 the contributing agency without reimbursement,
21 and such detail shall be without interruption or
22 loss of civil service status or privilege.

23 “(b) DEFINITIONS.—Any term that is defined in sec-
24 tion 319L and that is used in this section shall have the

1 same meaning in this section as such term is given in sec-
2 tion 319L.

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated \$1,000,000 to carry out
5 this section for each of the fiscal years 2007 and 2008.”.

6 **SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED**
7 **BY PROJECT BIOSHIELD.**

8 (a) QUALIFIED COUNTERMEASURES.—Section
9 319F–1(a)(2) of the Public Health Service Act (42 U.S.C.
10 247d–6a(a)(2)) is amended—

11 (1) by amending subparagraph (A) to read as
12 follows:

13 “(A) diagnose, mitigate, prevent, or treat
14 harm from any biological agent (including orga-
15 nisms that cause an infectious disease) or toxin,
16 or from any chemical, radiological, or nuclear
17 agent, that may cause a public health emer-
18 gency affecting national security; or”;

19 (2) in subparagraph (B), by striking “treat,
20 identify, or prevent harm” and inserting “diagnose,
21 mitigate, prevent, or treat harm”; and

22 (3) by adding after and below subparagraph
23 (B) the following:

24 “If through publication in the Federal Register the
25 Secretary makes a determination that there is cred-

1 ible evidence that a biological agent has the potential
 2 to cause an epidemic or pandemic that may con-
 3 stitute a public health emergency, a countermeasure
 4 to such agent shall, without further administrative
 5 action, be considered a qualified countermeasure
 6 within the meaning of this paragraph.”.

7 (b) SECURITY COUNTERMEASURES.—Section 319F–
 8 2(c)(1)(B)(i)(I) of the Public Health Service Act (42
 9 U.S.C. 247d–6b(c)(1)(B)(i)(I)) is amended by striking “to
 10 treat” the first place such term appears and all that fol-
 11 lows through “from a condition” and inserting the fol-
 12 lowing: “to diagnose, mitigate, prevent, or treat harm
 13 from any biological agent (including organisms that cause
 14 an infectious disease) or toxin or from any chemical, radio-
 15 logical, or nuclear agent identified as a material threat
 16 under paragraph (2)(A)(ii), or to diagnose, mitigate, pre-
 17 vent, or treat harm from a condition”.

18 **SEC. 5. TECHNICAL ASSISTANCE.**

19 Subchapter E of chapter V of the Federal Food,
 20 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
 21 amended by adding at the end the following:

22 **“SEC. 565. TECHNICAL ASSISTANCE.**

23 “The Secretary, in consultation with the Commis-
 24 sioner of Food and Drugs, shall establish within the Food
 25 and Drug Administration a team of experts on manufac-

1 turing and regulatory activities (including compliance with
 2 current Good Manufacturing Practice) to provide both off-
 3 site and on-site technical assistance to the manufacturers
 4 of qualified countermeasures (as defined in section 319F–
 5 1 of the Public Health Service Act), security counter-
 6 measures (as defined in section 319F–2 of such Act), or
 7 vaccines, at the request of such a manufacturer and at
 8 the discretion of the Secretary, if the Secretary determines
 9 that a shortage or potential shortage may occur in the
 10 United States in the supply of such vaccines or counter-
 11 measures and that the provision of such assistance would
 12 be beneficial in helping alleviate or avert such shortage.”.

13 **SEC. 6. PROCUREMENT.**

14 Section 319F–2 of the Public Health Service Act (42
 15 U.S.C. 247d–6b) is amended—

16 (1) in the section heading, by inserting “**AND**
 17 **SECURITY COUNTERMEASURE PROCUREMENTS**” before the period; and
 18

19 (2) in subsection (c)—

20 (A) in the subsection heading, by striking
 21 “BIOMEDICAL”;

22 (B) in paragraph (5)(B)(i), by striking “to
 23 meet the needs of the stockpile” and inserting
 24 “to meet the stockpile needs”;

25 (C) in paragraph (7)(B)—

1 (i) by striking the subparagraph head-
2 ing and all that follows through “Home-
3 land Security Secretary” and inserting the
4 following: “INTERAGENCY AGREEMENT;
5 COST.—The Homeland Security Sec-
6 retary”; and

7 (ii) by striking clause (ii);
8 (D) in paragraph (7)(C)(ii)—

9 (i) by amending clause (I) to read as
10 follows:

11 “(I) PAYMENT CONDITIONED ON
12 DELIVERY.—The contract shall pro-
13 vide that no payment may be made
14 until delivery of a portion, acceptable
15 to the Secretary, of the total number
16 of units contracted for, except that,
17 notwithstanding any other provision of
18 law, the contract may provide that, if
19 the Secretary determines (in the Sec-
20 retary’s discretion) that an advance
21 payment, partial payment for signifi-
22 cant milestones, or payment to in-
23 crease manufacturing capacity is nec-
24 essary to ensure success of a project,
25 the Secretary shall pay an amount,

1 not to exceed 10 percent of the con-
2 tract amount, in advance of delivery.
3 The Secretary shall, to the extent
4 practicable, make the determination of
5 advance payment at the same time as
6 the issuance of a solicitation. The con-
7 tract shall provide that such advance
8 payment is required to be repaid if
9 there is a failure to perform by the
10 vendor under the contract. The con-
11 tract may also provide for additional
12 advance payments of 5 percent each
13 for meeting the milestones specified in
14 such contract. Provided that the spec-
15 ified milestones are reached, these ad-
16 vance payments of 5 percent shall not
17 be required to be repaid. Nothing in
18 this subclause shall be construed as
19 affecting the rights of vendors under
20 provisions of law or regulation (in-
21 cluding the Federal Acquisition Regu-
22 lation) relating to the termination of
23 contracts for the convenience of the
24 Government.”; and

1 (ii) by adding at the end the fol-
2 lowing:

3 “(VII) PROCUREMENT OF MUL-
4 TIPLE PRODUCTS AND TECH-
5 NOLOGIES.—The Secretary may enter
6 into multiple transactions for the pro-
7 curement of multiple technologies and
8 products from multiple manufacturers
9 of security countermeasures in order
10 to mitigate against the risks associ-
11 ated with dependence on a single sup-
12 plier or technology.

13 “(VIII) SALES EXCLUSIVITY.—
14 The contract may provide that the
15 vendor is the exclusive supplier of the
16 product to the Federal Government
17 for a specified period of time, not to
18 exceed the term of the contract, on
19 the condition that the vendor is able
20 to satisfy the needs of the Govern-
21 ment. During the agreed period of
22 sales exclusivity, the vendor shall not
23 assign its rights of sales exclusivity to
24 another entity or entities without ap-
25 proval by the Secretary. Such a sales

1 exclusivity provision in such a con-
2 tract shall constitute a valid basis for
3 a sole source procurement under sec-
4 tion 303(c)(1) of the Federal Property
5 and Administrative Services Act of
6 1949 (41 U.S.C. 253(c)(1)).

7 “(IX) SURGE CAPACITY.—The
8 contract may provide that the vendor
9 establish domestic manufacturing ca-
10 pacity of the product to ensure that
11 additional production of the product is
12 available in the event that the Sec-
13 retary determines that there is a need
14 to quickly purchase additional quan-
15 tities of the product. Such contract
16 may provide a fee to the vendor for
17 establishing and maintaining such ca-
18 pacity in excess of the initial require-
19 ment for the purchase of the product.
20 Additionally, the cost of maintaining
21 the domestic manufacturing capacity
22 shall be an allowable and allocable di-
23 rect cost of the contract.

24 “(X) ADDITIONAL CONTRACT
25 TERMS.—The Secretary, in any con-

1 tract for procurement under this sec-
2 tion, may specify—

3 “(aa) the dosing and admin-
4 istration requirements for coun-
5 termeasures to be developed and
6 procured;

7 “(bb) the amount of funding
8 that will be dedicated by the Sec-
9 retary for development and ac-
10 quisition of the countermeasure;
11 and

12 “(cc) the specifications the
13 countermeasure must meet to
14 qualify for procurement under a
15 contract under this section.”; and

16 (E) in paragraph (8)(A), by adding at the
17 end the following: “In the case of such agree-
18 ments by the Secretary, the Secretary may
19 allow other executive agencies to order qualified
20 and security countermeasures under procure-
21 ment contracts or other agreements established
22 by the Secretary, and such ordering process (in-
23 cluding transfers of appropriated funds between
24 an agency and the Department of Health and
25 Human Services as reimbursements for such or-

1 ders for countermeasures) may be conducted
2 under the authority of section 1535 of title 31,
3 United States Code, except that all such orders
4 shall be processed under the terms established
5 under this section for the procurement of coun-
6 termeasures.”

Passed the House of Representatives September 26,
2006.

Attest:

KAREN L. HAAS,
Clerk.